

Application No.: 09/955,502

Amendment dated: March __, 2005

Reply to Office Action Dated: October 18, 2004

REMARKS

In a Final Office Action mailed on October 18, 2004 in the above-identified application, claim 1 and 7-10 are currently pending and under examination. Claim 15 is withdrawn from consideration as being drawn to a non-elected invention. Claims 2-6 and 11-14 had been cancelled before the Examiner's review. Claims 1 and 7-10 were rejected.

Specifically, the Office Action has substantively rejected claims 1, 7-10 under 35 U.S.C. §112, first paragraph (written description); claims 1, 7, and 8 under 35 U.S.C. §112, second paragraph (indefiniteness); and claims 1, 7 and 8 under 35 U.S.C. §102(b).

Applicants submit that each rejection has been separately addressed below. Accordingly, in light of the amendments above and the arguments below, Applicants respectfully request reconsideration.

At the outset, Applicants acknowledge and thank the Examiner for withdrawing the rejection of claims 1-14 under 35 U.S.C. 112, second paragraph in view of amendments to the claims. Similarly, Applicants acknowledge and thank the Examiner for withdrawing the 35 U.S.C. 102(b) rejections of claims 1, 2, and 4-7 as being anticipated by Portnoy, *et al.*, Kelner, *et al.*, and Ben-Amor, *et al.*, respectively in view of the Applicants' claim amendments to recite "eubacterial cell."

On February 3, 2005, Applicants' attorney Jean C. Baker telephonically interviewed this case with Examiner Duffy. Applicants and their attorneys thank Examiner Duffy for the courtesy of her time and for her helpful suggestions.

During that interview, Applicants' attorney addressed all pending rejections. While no resolution of the rejections were made, Examiner Duffy made some suggestions to Applicants which are incorporated in Applicant's response. Applicants have specifically commented on the interview in describing their response below.

In summary and as a result of Applicants' conversations with Examiner Duffy, Applicants have now presented claim 1, drawn to the YggX gene of SEQ ID NO:11; claim 16, drawn to a YggX homolog of SEQ ID NO:1; claim 17, drawn to particular YggX homologs disclosed in provisional application 60/234,588, from which the above-identified case claims priority; claim 18, drawn to YggX homologs listed in Fig. 1. Claims 9 and 10

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have been cancelled and rewritten as claims 19-26, which follow the same structure as claims 1, 16, 17 and 18.

Election/Restrictions

The Examiner asserts that a complete reply to the final rejection must include cancellation of non-elected claim 15 or other appropriate action (37 CFR 1.144) See MPEP 821.01. Applicants hereby withdraw claim 15.

Claim Rejections – 35 U.S.C. §112, first paragraph

Claims 1 and 7-10 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner asserts that claims 1, 7 and 8 reciting “YggX” does not convey a common structure and that the claims “include numerous structural variants … because a significant number of structural differences between genus members are permitted.”

In response to the Examiner’s rejection, Applicants have clarified that the “YggX gene” of claim 1 is identical to SEQ ID NO:11, the nucleotide sequence of the YggX gene presented in the specification. In the February 3rd phone call with Examiner Duffy, Applicants’ attorney described a GenBank sequence number within the application and told Examiner Duffy that Applicants would retrieve this sequence and insert it into the application. Applicants’ attorney did not realize during the conversation that YggX sequence was already in the application at SEQ ID NO:11. (Applicants draw the Examiner’s attention to the March 6, 2002 sequence listing submission which includes a relabeled Fig. 1.)

Furthermore, the Examiner asserts that the specification is “limited to methods that reduce superoxide damage to an eubacterial cell comprising vector-based over-expression of the endogenous YggX gene from said cell, wherein said overexpression renders the cells more resistant to superoxide damage.” In response, Applicants submit that the claimed invention should not be limited to vector-based over-expression of the endogenous YggX gene. To demonstrate that the claimed invention is equally applicable to vector-based over-expression of endogenous and exogenous YggX genes, Applicants submit herewith the

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Declaration of Professor Diana Downs. Dr. Down's Declaration provides that heterologous bacterial expression systems are well known and widely accepted in the art of bacteriology.

Note paragraph 4 of Dr. Downs' Declaration, where she cites numerous publications describing work where proteins have been expressed and characterized in heterologous systems as helping to demonstrate that the invention should not be limited to methods that reduce superoxide damage to eubacterial cells having factor-based overexpression only of the endogenous YggX gene.

Also, claims 9 and 10 stand rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Specifically, the Examiner asserts that independent claim 9 does not recite a sequence identifier as it relates to the YggX gene homolog and that a significant number of structural differences between genus members are permitted.

In response, for clarity purposes and an effort to prevent a need for an appeal Applicants have resubmitted claims 9 and 10 as new claims 19-26. Claims 19 and 20 have been amended to recite SEQ ID NO:11. Claims 21 and 22 have been drawn to specific homologs recited in U.S. Serial No. 60,234,588. Claims 23 and 24 are drawn to homologs comprising consensus sequence SEQ ID NO:1. Claims 25 and 26 are drawn to homologs recited in Fig. 1. Therefore, Applicants submit that in view of the amendment and the above remarks the application as filed does provide sufficient written description.

Priority and Claim Rejections – 35 U.S.C. §102

The Examiner asserts that the specification does not provide sufficient written description for SEQ ID NO:1 and that the figures do not provide conception of SEQ ID NO:1.

As per Applicants' conversation with Examiner Duffy, Applicants have now submitted revised claims. Claim 1 does not contain the SEQ ID NO:1 language but drawn to a particular YggX sequence. Claim 16 contains the "SEQ ID NO:1" language. Claim 17 lists as homologs the group of homologs disclosed in provisional application 60/234,588.

Furthermore, Applicants have amended paragraph [0026] of the specification to include the sequence identifier SEQ ID NO:11 for the amino acid sequence of the *E. coli* YggX as listed at GenBank Accession No. AAC75999. Applicants submit that the

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introduction of SEQ ID NO:11 in the specification is not new matter because SEQ ID NO:11 and GenBank Accession No. AAC75999 both correspond to the *Escherichia coli* K12 YggX gene which is supported by Figure 1A as originally filed. MSRTIFCTFL QREAEGQDFQ LYPGELGKRI YNEISKEAWA QWQHKQTMLI NEKKLNMMNA EHRKLLEQEM VNFLFEGKEV HIEGYTPEDK K. This YggX *E. coli* K12 amino acid sequence directly corresponds to SEQ ID NO:11 (*E. coli*) in Figure 1A.

Claims 1, 7 and 8 stand rejected under 35 U.S.C. §102(b) as being anticipated by Gralnick, *et al.*, (Abstracts of the General Meeting of the American Society for Microbiology, 100 Pg. 441 (May 21-25, 2000)). In response, Applicants resubmit herewith a copy of the declaration concurrently filed with the previous response attesting that the identity of the Abstract's authors is the same as the Applicants. Applicants submit that Gralnick, *et al.* is not publication "by another" and cannot stand as a § 102(b) reference.

Claims 1 and 7 stand rejected under 35 U.S.C. §102(b) as being anticipated by Pianzzola, *et al.*, (*J. Bacteriology* 178(23):6736-6742, 1996). The Examiner asserts that Pianzzola, *et al.*, teaches that the corresponding rbo protein in *Dulfovibrio vulgaris* encodes a putative rubredoxin oxidoreductase. Further, Pianzzola, *et al.* admit the gene as not being related to any known superoxide dismutase proteins (see page 6738, column 2, last sentence). Pianzzola, *et al.* teach that the function of rbo is unknown. Pianzzola, *et al.* conclude that rbo appears to be a new way to fight oxidative stress. The Examiner also asserts that in view of the lack of structure for YggX recited in the claims and in view that the rbo gene product functions the same, it meets the limitation of YggX protein. The Examiner further asserts that recitation of YggX in the claim does not patently distinguish the methods from other methods using differently named proteins that have the same functional effect.

In response, Applicants submit that they have now identified the YggX gene so that it is distinct from any of the Pianzzola disclosure. Accordingly, Applicants strongly submit that the disclosure of Pianzzola, *et al.*, does not anticipate the claims of the present invention.

Claim Rejections – 35 U.S.C. §112, second paragraph

Claims 1, 7 and 8 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Specifically, the Examiner asserts that the claims do not clarify that the vector-

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based expression is in a eubacterial cell. In response, Applicants have amended claim 1 and new claims 16-24 to clarify the location of the expression.

Furthermore, claims 1, 7 and 8 stand rejected under 35 U.S.C. 112, second paragraph, because allegedly the term "increased" is indefinite because the claims do not define what the increase is relative to. In response, for clarity purposes Applicants have amended independent claims 1 and new claims 16-26 to recite that the "increase" is relative to cells not expressing the YggX protein or the homolog thereof.

Accordingly, in view of the above claim amendments and remarks, the application is now believed to be in condition for allowance. Applicants respectfully request that a timely Notice of Allowance be issued in this case.

A three month petition for extension of time and RCE is filed herewith so this response will be considered as timely filed. Please charge the extension fee to Deposit Account No. 17-0055. If any other fee is due, please consider this to be a request to charge the fee to Deposit Account No. 17-0055.

Respectfully submitted,



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